

### **REMARKS/ARGUMENTS**

The Examiner is reminded that the instant Application has been made special by the USPTO and respectfully requests expedited examination.

### **CLAIM OBJECTION/REJECTIONS**

Claims 15-18 and 21-36 are under examination in the instant application. The following rejections/objections were listed in the Final Office Action mailed December 31, 2007.

1. Claims 21-29 were objected to.
2. Claims 15-18 and 21-36 were rejected under 35 U.S.C. 112, first paragraph.

Applicant addresses each of the objections/rejection below.

#### ***Claim Objection – Claim 21-23 are objected too***

The Action objects to claims 21-23. Claims 21-23 as amended over come these objections. As a result Applicant respectfully requests that the objection be withdrawn.

#### ***Claim Objection – Claim 24-29 are objected too***

The Action also objects to claims 24-29 under 37 CFR 1.75(c) as being in improper form, because a multiple dependent claim cannot depend from any other multiple dependent claim. See MPEP § 608.01(n). However, the Applicant fails to recognize a multiple dependent claim depending from another multiple dependent claim. Claim 15 is an independent claim, and the presence of an alternative expression in the claim does not render the claim a multiple dependent claim. The term “multiple dependent claim” is defined in MPEP § 608.01(n) as “Any dependent claim which **refers to more than one other claim** ("multiple dependent claim") shall refer to such other claims in the alternative only. Therefore claim 15 is not a multiple dependent claim. Therefore, there is no multiple dependent claim that depends from another multiple dependent claim. There is a dependent claim that depends from a multiple dependent claim, but that is acceptable under MPEP § 608.01(n). Clarification is respectfully requested.

As such, Applicant respectfully requests the withdrawal of the objections to claims 21-29.

***Claim Rejections – Claim 15-18 and 21-36 is rejected under 35 U.S.C. § 112, First paragraph***

The Action rejects claim 15-18 and 21-36 under 35 U.S.C. § 112 First paragraph as lacking enablement. The Action states that:

Specification, white (*sic*) being enabling for accelerating the growth rate of a prematurely-born human infant with **triheptanoin**, does not enablement for any seven carbon fatty acids or derivative thereof (straight or branched chain of seven carbons with any substitution).(emphasis added)

The claims at issue are not drawn to **any seven carbon fatty acids** or derivative thereof but selected acids and derivatives, i.e., triheptanoin or n-heptanoic acid or derivatives. The Examiner is directed to the claims at issue, for example:

Claim 15 (currently amended) A method of suppressing the effects of translocase deficiency—a prematurely-born human infant by administering to an infant suspected of having a translocase deficiency a composition comprising a **seven carbon fatty acid selected from triheptanoin or n-heptanoic acid or derivatives thereof**. (emphasis added)

The instant claims of the are not directed to ANY or EVERY seven carbon fatty acid but to a seven carbon fatty acid **selected from triheptanoin or n-heptanoic acid or derivatives** thereof. The specification enables the skilled artisan to practice the present invention without undue experimentation. (See M.P.E.P. § 2164.02).

Applicant submits that the claims are fully enabled for the skilled artisan to practice the present invention without undue experimentation. The present invention clearly defines the compositions at issue in the instant application. For example, paragraph [0070] of the instant application defines specific seven carbon fatty acid and provides the structure for n-heptanoic acid and further defines triheptanoic acid. Therefore, the specific compounds are clearly enabled. In addition, the terms “derivatives thereof” are also fully enabled and allow the skilled artisan to practice the present invention without undue experimentation. For example, the instant specification clearly defines and enables the use of derivatives thereof throughout the specification, e.g., see paragraphs [0013, 0070, 0074].

The Applicant asserts that the specification as disclosed compiles with 35 U.S.C. § 112 and does not require undue experimentation. The present invention relates to and provides

examples of seven carbon fatty acids and includes variations of that fatty acid, e.g., substituted, unsaturated or branched heptanoates. The properties of fatty acids are well known in the art and the effects of modifications to the fatty acids are also well known in the art. Therefore, the “representative number of species” presented in the specification are adequately described and are representative of the entire genus (e.g., straight or branched chain of seven carbons with any substitution) and describes the species to reflect the variation within the genus. See, *In re Herschler*, 591 F.2d 693, 697, 200 USPQ 711, 714 (CCPA 1979) (disclosure of corticosteroid in DMSO sufficient to support claims drawn to a method of using a mixture of a “physiologically active steroid” and DMSO because “use of known chemical compounds in a manner auxiliary to the invention must have a corresponding written description only so specific as to lead one having ordinary skill in the art to that class of compounds. Occasionally, a functional recitation of those known compounds in the specification may be sufficient as that description.”). As is the case here, the functional recitation of those known compounds in the specification are sufficient.

As stated above, the specification provides guidance to the compounds and the nature of the derivatives and as such the skilled artisan can easily predictable given the instant specification.

Again it is UNCLEAR where the Action is deriving the statement regarding the examples of the present invention being limited, See below:

The working examples are limited to an *in vitro* cell culture assay of cells derived from a deceased infant, a single cell culture derived from a fetus, and a single *in vivo* example treating an infant with triheptanoin-supplemented formula only. There is no showing drawn to the critical elements of a predictable acceleration of growth rate of a prematurely-born human infant, wherein said infant obtains nutrition from odd carbon fatty acid  $\beta$ -oxidation and wherein the composition comprising said seven-carbon chain fatty acid is adapted for consumption in one or more doses and said doses comprise 15%-40% of the dietary caloric requirement for said infant for 24 hours.

The specification as filed provides numerous examples of the present invention in cell lines:

EXAMPLE 1 Supplementation in Cell Lines

[0082] The addition of n-heptanoic acid to cultured cells (fibroblasts) taken from patients with a lethal form of translocase deficiency indicated successful oxidation.

And in ACTUAL use to TREAT an INFANT suffering from a translocase deficiency:

EXAMPLE 2 *In Vivo* Utilization of Triheptanoin Supplementation in Severe Translocase-Deficient Patient

[0091] Treatment of the infant with severe neonatal translocase deficiency identified in Example 1 **using triheptanoin-supplemented low fat formula was successful**. Additionally, there is support

for the correlation between the clinical response to triheptanoin therapy and the in vitro mass spectrometry analysis of the infant's amniocytes. Emphasis added.

The examples present in the instant specification more than adequately enables various claimed compositions and derivatives thereof and enable the present invention to be used to accelerate the growth of prematurely-born human infants.

Applicant submits that the claims as amended fully comply with the requirements of 35 U.S.C. § 112 and allow the skilled artisan to practice the present invention without undue experimentation. As such, withdrawal of the rejections and an early notice of allowance is respectfully requested.

**Conclusion**

In light of the remarks and arguments presented above, Applicant respectfully submits that the claims in the instant Application are in condition for allowance. Favorable consideration and allowance of the pending Claims 15-18, and 21-36 are therefore respectfully requested.

If the Examiner has any questions or comments, or if further clarification is required, it is requested that the Examiner contact the undersigned at the telephone number listed below.

Dated: February 29, 2008.

Respectfully submitted,



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